

JUL 25 1997



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Charles E. Van Horn
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005-3315

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,814,470

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,814,470, which claims the human drug product TAXOTERE® (docetaxel), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,035 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of November 29, 1996 (61 Fed. Reg. 60,710). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,358) + 658 \\ &= 1,337 \text{ days (3.66 years)}\end{aligned}$$

Since the regulatory review period began November 8, 1990, after the patent issue date (March 21, 1989), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (May 14, 1996) when added to the period of extension calculated above (1,337 days) cannot exceed fourteen years. The period of extension is thus limited to May 14, 2010, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of twenty-years from the filing date (35 U.S.C. § 154) would expire on July 14, 2007, the period of extension is the number of days to extend the term of the patent from its expiration date to and including May 14, 2010, or 1,035 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,035 days.

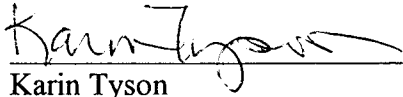
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,814,470
Granted	:	March 21, 1989
Original Expiration Date	:	July 14, 2007
Applicant	:	Michel Colin et al.
Owner of Record	:	Rhone-Poulenc Rorer S.A.
Title	:	Taxol Derivatives, Their Preparation and Pharmaceutical Compositions Containing Them
Classification	:	514/449
Product Trade Name	:	TAXOTERE®
Term Extended	:	1,035 days
Expiration Date of Extension	:	May 14, 2010

Any correspondence with respect to this matter should be addressed as follows:

- By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231
- By FAX: (703) 308-6916
Attn: Special Program Law Office
- By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson

Legal Advisor

Special Program Law Office

Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: TAXOTERE®
FDA Docket No.: 96E-0271